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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,228	02/21/2002	Shuji Hinuma	46342/57113	1875

21874 7590 10/25/2006

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,228	Applicant(s) HINUMA ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1) Claims 3 and 13 to 16 are pending in the instant application. Claim 3 has been amended, claims 1 and 12 have been canceled and claims 13 to 16 have been added as requested by Applicant in the correspondence filed 10 August of 2006.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 3 and 13 to 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is vague and indefinite because there is no antecedent basis for "the thus selected test compounds". Further, because section "(ii)" requires "selecting the test compound that has..." the reference to "a common structure" in section "(iii)" makes no sense. Claims 13 to 16 are vague and indefinite in so far as they depend from claim 13 for these elements.

5 & 6) Claims 3, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by each of the Zhou et al. (P.N.A.S. 89:7432-7436, Aug. 1992, of record) and Samson et al. (Biochemistry 35:3362-3367, 1996) publications. Figure 1 on page 7434 of Zhou et al. and Figure 1 of page 3364 of Samson et al. each described an isolated orphan receptor protein, identified therein as R226 and ChemR13 respectively, and a process of determining the identity of possible ligands for that receptor by comparing the amino acid sequence of that receptor with the sequences of related receptors for which ligands had been identified. Figure 4 on page 7435 of Zhou et al.

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and Figure 3 on page 3366 of Samson et al. described binding assays that fully anticipate the instant claims. In describing the experiment presented in Figure 4 therein, the first paragraph on page 7434 of Zhou et al. stated that "[I]ncubation of wild-type and R226 stably transfected CHO cells with 1 μ M forskolin resulted in a 15-fold increase in cellular cAMP levels" and that "[I]n wild-type CHO cells, adenosine agonists had no effect on forskolin-stimulated cAMP production.

The Zhou et al. and Samson et al. publications, when taken in combination, show that the practice of identifying ligands for an orphan receptor by selecting test compounds based upon the similarity of that orphan receptor to receptors having known ligands, and then testing the ligands for those related receptor, and compounds related thereto, for the ability to bind to the orphan receptor was routine in the art long before the making of the instant invention.

7) Claims 3 and 13 to 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Samson et al. publication cited above. Given the disclosure by Samson et al. that the orphan receptor protein described therein was activated by proteins of the chemokine family, and specifically by the naturally occurring and structurally related proteins MIP-1 α , MIP-1 β and RANTES, that artisan would have found it *prima facie* obvious to search for additional receptor ligands based upon anticipated structural similarities to these three proteins. As shown by Figure 1 of Samson et al., it was routine in the art to identify structurally related proteins by searching for amino acid sequence similarities, and the practices of identifying such similarities through direct sequence comparison as illustrated by that figure, by

observing immunological cross-reactivity, or through cDNA hybridization as described in the section entitled "*Cloning and Sequencing*" on page 3363 of Samson et al. were well established in the art of molecular biology before the time of the instant invention. To employ any one or more of those methods in the identification of additional chemokines which activate the receptor protein of Samson et al. would have been obvious to the skilled artisan in view of that publication.

8) Applicant's arguments with respect to claims 3 and 13 to 16 have been considered but are moot in view of the new ground(s) of rejection.

9) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JOHN ULM
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